K130753

JUN 1 3 2013

8 510(k) Summary

Submitter:	WatchDog Group, LC 7800 Forsyth Blvd 8th Floor St. Louis, MO 63105
Contact Persons:	Primary Contact: John O'Hara WatchDog Group, LC 7800 Forsyth Blvd 8th Floor, St. Louis, MO 63105 Phone: 314-721-5367; Fax: 314-725-5873, email: LensAlert@aol.com Secondary Contact: Maggie Genovese (Same address as above) Phone: 314-721-5367; Fax: 314-725-5873; email: MaggieLensAlert@aol.com
Date Prepared:	June 12, 2013
Trade Names:	Color Case Contact Lens Case; Flip N Slide Contact Lens Case
Classification:	21 CFR 886.5928; Soft (hydrophilic) contact lens care products, Class II
Product Code:	LRX
Predicate Device:	Contact lens cases by Ningbo Kaida Rubber & Plastic Technology Co., LT (k071081)
Device Description:	The contact lens cases are designed for storage of contact lenses. The Color Case Contact Lens Case has 2 adjoining wells that have screw top caps. The Flip N Slide Contact Lens Case model has 2 adjoining wells with integral hinged, self-sealing caps in which contact lenses are immersed. The devices are not sterile and are not for heat disinfection. They are made of polypropylene plastic. The volume capacity is 5.91 ml on each well of both lens cases.
Intended Use:	Intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.
Comparison of Technological Characteristics:	Similar to the predicate, both the Color Case Contact Lens Case and the Flip N Slide Contact Lens Case have 2 adjoining wells with top caps designed to hold contact lenses and their chemical disinfectant solutions. Similar to several of the contact lens cases encompassed by the predicate premarket notification (k071081), both the Color Case Contact Lens Case and the Flip N Slide Contact Lens Case are composed of polypropylene plastic. The new Color Case Contact Lens Case uses separate screw caps, as does the predicate. The Flip N Slide Contact Lens Case model differs from the predicate in that it has integral, self-sealing caps instead of separate screw top caps. This difference does not pose new questions of safety and effectiveness, as the integral cap design achieves the same outcome of securing the contact lenses and disinfectant solutions in the wells.
Non-Clinical Testing:	Extraction testing was conducted and demonstrated there were no leachable organic compounds above the pre-determined detection limit. Biocompatibility testing has been conducted on the materials and met acceptance criteria.
Clinical Testing	Not Applicable
Conclusion:	The physical design, materials and intended use of the new devices are substantially equivalent to those of the predicate device and any differences do not pose new questions of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

June 13, 2013

Mr. John O'Hara
President
Watchdog Group, LC
7800 Forsyth Blvd., 8th Floor
Clayton, MO 63105

Re: K130753
Trade/Device Name: Color Contact Lens Case; Flip n Slide Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Contact Lens Case
Regulatory Class: Class II
Product Code: LRX
Dated: May 7, 2013
Received: May 10, 2013

Dear Mr. O'Hara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina Eydelman
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K130753

Device Names:

- Color Contact Lens Case
- Flip N Slide Contact Lens Case

Indications for Use:

Intended for the storage of soft (hydrophilic), rigid gas permeable (RGP), or hard contact lenses during chemical disinfection. For use in storage during chemical disinfection only. Do not use during heat disinfection.

Prescription Use_____ AND/OR Over-The-Counter Use___X___

(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Leonid Eivshitz -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
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